



DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

04-PHI-02

WARNING LETTER

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

February 25, 2004

Mr. Gary Charlestein, Chief Executive Officer
Premier Medical, Division of Premier Dental Products Co.
10090 Sandmeyer Lane
Philadelphia, Pennsylvania 19116-3502

Dear Mr. Charlestein:

During an inspection of your establishment located in Philadelphia, Pennsylvania, which ended on November 26, 2003, our investigator determined that your firm manufactures Nitrospray Plus and Nitrospray Plus Lite (Nitrospray) units. The Nitrospray units are medical devices within the meaning of Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated under section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Failure to document the identification, review, and approval of cap/seal design changes to the above subject Nitrospray devices before these design changes were implemented as required by 21 CFR 820.30(i). These devices with cap/seal design changes have been distributed to customers.
2. Failure to document the identification, review, and approval of a Nitrospray retrofit sealing system kit as required by 21 CFR 820.30(i). This seal ring retrofit kit was designed to modify those Nitrospray devices manufactured before the above cap/seal design change was implemented. This seal ring retrofit kit has also been distributed to customers.
3. Failure to document validation of the above cap/seal, and seal ring retrofit kit design changes to verify that the subject devices conform to defined user needs and intended uses as required by 21 CFR 820.30(g).

Additionally, the above-stated inspection revealed that your devices are misbranded under section 502(t)(2) of the Act, in that your firm failed or refused to furnish any material or information required by or under section 519 respecting the device and 21 CFR Part 803 (Medical Device Reporting regulation). Specifically, you failed to submit a report to FDA after receiving information which reasonably suggested that one of your commercially distributed devices may have caused or contributed to a serious injury.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no applications for premarket approval of Class III devices to which the Quality System regulation deficiencies are reasonably related will be approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be granted until the violations related to the subject devices have been corrected.

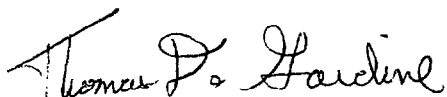
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to William J. Forman, Compliance Officer, Food and Drug Administration, 2nd & Chestnut Streets, Room 900, Philadelphia, Pennsylvania 19106.

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Sincerely yours,

A handwritten signature in cursive script that reads "Thomas D. Gardine". The signature is written in dark ink and is positioned above the typed name.

Thomas D. Gardine
District Director
Philadelphia District Office
Food and Drug Administration

Cc:

Pennsylvania State Department of Health
132 Kline Plaza, Suite A
Harrisburg, Pennsylvania 17104
Attention:
Robert E. Bastian, Director
Division of Primary Care and Home Health Services